Responsiveness and Clinical Utility of the Geriatric Self-Efficacy Index for Urinary Incontinence

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Abstract

OBJECTIVES: To report on the responsiveness testing and clinical utility of the 12-item Geriatric Self-Efficacy Index for Urinary Incontinence (GSE-UI).
DESIGN: Prospective cohort study.
SETTING: Six urinary incontinence (UI) outpatient clinics in Quebec, Canada.
PARTICIPANTS: Community-dwelling incontinent adults aged 65 and older.
MEASUREMENTS: The abridged 12-item GSE-UI, measuring older adults' level of confidence for preventing urine loss, was administered to all new consecutive incontinent patients 1 week before their initial clinic visit, at baseline, and 3 months posttreatment. At follow-up, a positive rating of improvement in UI was ascertained from patients and their physicians using the Patient's and Clinician's Global Impression of Improvement scales, respectively. Responsiveness of the GSE-UI was calculated using Guyatt's change index. Its clinical utility was determined using receiver operating curves.
RESULTS: Eighty-nine of 228 eligible patients (39.0%) participated (mean age 72.6+5.8, range 65–90). At 3-month follow-up, 22.5% of patients were very much better, and 41.6% were a little or much better. Guyatt's change index was 2.6 for patients who changed by a clinically meaningful amount and 1.5 for patients having experienced any level of improvement. An improvement of 14 points on the 12-item GSE-UI had a sensitivity of 75.1% and a specificity of 78.2% for detecting clinically meaningful changes in UI status. Mean GSE-UI scores varied according to improvement status ($P<.001$) and correlated with changes in quality-of-life scores ($r=0.7$, $P<.001$) and reductions in UI episodes ($r=0.4$, $P=.004$).
CONCLUSION: The GSE-UI is responsive and clinically useful.

The Geriatric Self-Efficacy index for Urinary Incontinence (GSE-UI) is a new valid and reliable outcome measure for urinary incontinence (UI).[1] An advantage of the GSE-UI is its ability to measure one of the psychological factors potentially underlying continence status: confidence or self-efficacy for preventing unwanted urine loss. Self-efficacy, the belief a person has in his or her ability to perform specific behaviors, has been shown to be an important factor for improving outcomes in other geriatric conditions, such as falls.[2–4] Its application to UI is threefold: the promise that self-efficacy holds as a causal explanatory mechanism for UI, as an alternate therapeutic method, and as a new outcome measure to study the effect of UI interventions.

Empirical research suggests a role for self-efficacy in the field of incontinence. For example, greater self-efficacy for achieving continence may partially explain the impressive 32% to 65% reductions in UI seen during placebo treatment in randomized controlled pharmaceutical trials of UI.[5] Increased self-efficacy may

also account for some of the results of behavioral and combined modality treatment trials, whereby changes in urodynamic or voiding frequency parameters do not fully explain improvements in UI.[6–7]
Although a number of UI outcome measures exist, there is substantial evidence that they are rarely used in clinical practice.[8,9] As such, there is no value in creating another clinical UI tool unless it is constructed to meet the realities of busy clinicians and their clinical environment. Having demonstrated the reliability and validity of the 20-item GSE-UI, it was deemed important to create a shorter version and test its psychometric properties. This article reports on three specific objectives. The first is the reduction of items on the GSE-UI from the 20-item to the 12-item version. The second is the psychometric evaluation of the responsiveness of the 12-item version. The third is the evaluation of the clinical utility of the 12-item GSE-UI, using different cutoff scores for measuring meaningful improvements in UI.

METHODS

Development of the 12-Item Index

The creation, validity, and reliability testing of the 20-item GSE-UI have previously been described.[1] To create a shorter index, 12 efficacy items were retained based on the following three criteria: a missing response rate ("does not apply to me" option) less than 30%; good to excellent item test–retest reliability, determined according to an intraclass correlation coefficient (ICC) greater than 0.6; and good patient comprehension, determined according to the patient's and research assistant's perspectives. Two original items "when walking 15 to 20 minutes" and "when taking a car ride for 30 minutes or longer" were eliminated based on ICCs of 0.57 and 0.59, respectively. Three items, "finding ways to distract yourself to overcome the urge to urinate,""spacing out trips to the bathroom so you do not go too frequently," and "running errands without having to stay near a washroom most of the time," were eliminated based on problematic comprehension by respondents requiring clarification of the question by the interviewer. For many patients, rewording of the questions did not significantly improve comprehension. One item ("when you are frustrated") was omitted because 43% of respondents indicated "does not apply to me," and two items ("when you are tired" and "when you feel depressed") had ICC and missing response item deficiencies. For the 12 items that were retained, phrasing and response scaling remained unchanged from the original index, whereby all items begin with "How confident are you that you can hold in your urine …" followed by a description of a specific situation[10] (e.g., "when you are at home and have to go to the bathroom?"). Response options are presented on a 10-point horizontal visual analogue scale with three anchors: 0 indicating "not at all confident I can do," 5 indicating "moderately confident I can do," and 10 indicating "extremely confident I can do." Item reduction testing was performed for the English and French versions of the scale and yielded identical results. The 12-item GSE-UI is presented in Table A1. Using the Cronbach alpha coefficient, the internal consistency of the 12-item GSE-UI was excellent (0.90).

Responsiveness and Clinical Utility Testing of the 12-Item GSE-UI

The responsiveness and clinical utility of the abridged 12-item GSE-UI were tested on a new sample of participants who had not been involved in the reliability and validity testing. These were new patients seeking care at outpatient urology, gynecology, or geriatric incontinence clinics in Montreal and Sherbrooke, Quebec, between September 2006 and October 2007. Patients who were aged 65 and older and who had symptoms of UI as defined by one or more episodes of involuntary urinary loss during the previous 3 months were eligible. Exclusion criteria were evidence of cognitive impairment indicated by a score less than 24 on the Mini-Mental State Examination,[11] other severe neurological or systemic conditions, and use of a permanent or intermittent urinary catheter.
The names of individuals who were to be seen in the clinic were provided to the study research assistant, who then contacted them in the weeks before their scheduled clinic appointment to determine their eligibility and willingness to participate in the study. Individuals who were eligible and consented met with the research assistant at three separate time points: 1-week before their initial scheduled UI clinic visit, again at the time of their first UI clinic visit, and at 3-month follow-up. During the initial visit, the following were administered: the 12-item GSE-UI; the Mini-Mental State Examination; and the International Consultation on Incontinence Questionnaire, a validated measure that queries the individual regarding UI frequency and amount and the circumstances under which UI occurs.[12] Patients were also instructed on how to complete a 72-hour bladder diary documenting the frequency of incontinence episodes and were asked to submit it at their next visit.[13]

One week later, when patients attended their scheduled UI clinic appointment, they also met with the research assistant, who administered the 12-item GSE-UI for a second time. The research assistant then asked whether the patient had experienced a change in UI during the past week, using the Patient's Global Impression of Improvement scale (PGI-I). The PGI-I is a validated, single-item global rating-of-change scale that asks patients to compare how their UI status is after treatment with how it was before treatment.[14] Seven responses are possible: very much better, much better, a little better, no change, a little worse, much worse, and very much worse. The Incontinence Quality of Life questionnaire, a validated 22-item UI-specific quality-of-life questionnaire on which higher scores indicate better quality of life, was also administered.[15,16] Participants also submitted their 72-hour bladder diary at this time. After consulting with their physician, all patients received a teaching session and standardized 12-week behavioral home management program including pelvic floor muscle training, distraction techniques, and lifestyle modification recommendations. Some patients also received pharmacological interventions or were scheduled for surgery.

At the 3-month follow-up visit, the same research assistant met with the patients to determine the patients' global impression of improvement in their UI condition using the PGI-I, to collect the second bladder diary, and to re-administer the GSE-UI and the Incontinence Quality of Life questionnaire. Afterward, patients met with their physician to discuss treatment effectiveness, and the physician was asked to document the Clinician's Global Impression of Improvement (CGI-I). The CGI-I is a clinician-rated single-item scale that uses the same 7-point response criteria as the PGI-I.[17] Physicians were blinded to all of the outcome scores collected specifically for this study. The clinician's diagnosis was used to classify UI type based on the patient's history and physical examination. The institutional review board of the Institut Universitaire de Gériatrie de Montréal, Quebec, Canada, approved the study.

Analysis

For each participant, the total score on the GSE-UI was calculated by summing the scores from each of the 12 items (minimum 0, maximum 10 points per item, range of total score 0–120). If one or more items were scored as “does not apply to me,” the item was omitted, and the total index score, calculated based on the number of items completed, was recalibrated on a scale of 120. To calculate a combined PGI-I and CGI-I score, each of the response options was assigned a numerical value from 1 to 7. An average of the two values was taken and rounded to the nearest full number, and then the average score for each participant was recategorized according to the original set of response options.

Guyatt's change index, applied to the total GSE-UI score, was used to test responsiveness. Guyatt's change index defined as the mean change in score in an improvement group divided by the standard deviation of the change in score in a stable group was used.[18–20] The stable group for this study was defined as participants who reported no change in UI status on the PGI-I during the week between baseline administrations of the 12-item GSE-UI. Two types of improvement groups were calculated using the 3-month follow-up data: patients experiencing “clinically meaningful improvement” and those experiencing “any improvement.” A participant was considered to have experienced a “clinically meaningful improvement” if the PGI-I and CGI-I ratings both indicated “very much better” or if one of the two ratings was “very much better” and the other “much better.” A participant was considered to have experienced “any improvement” if any other combination of “very much better,”“much better,” or “a little better” was obtained. Classifying the improvement groups for the responsiveness testing using a combination of PGI-I and CGI-I ratings of patients and physicians is an accepted method that has been used previously in other chronic disease states.[21,22] Guyatt statistics of 0.20, 0.50, and 0.80 or greater have been used to represent small, moderate, and large responsiveness, respectively.[20]

The clinical utility of the index was determined by selecting GSE-UI cutoff scores for improvement that simultaneously maximized the sensitivity and specificity for correctly classifying patients according to whether they fell in the clinically meaningful change group or the any improvement group. To do this, receiver operating characteristic (ROC) curves were constructed separately for each definition of improvement—the “clinically meaningful improvement” group and the “any improvement”—by plotting the sensitivity versus 1–specificity of different GSE-UI cutoff change scores for identifying members of

each group.[19] The ROC data point closest to the upper left-hand corner of each curve was used to indicate the most efficient cutpoint for differentiating patients whose UI status improved a specific amount (e.g., very much better) from those whose UI status had not changed by the specified amount.[22] The area under each ROC curve designates the probability of selecting the patient who improved by this specified amount from a set of two patients, one of whom did not improve by the specified amount. Specifically, the "clinically meaningful improvement" group was compared with all other patients, and the "any improvement" group was compared with those patients who experienced no change or worsening UI.

To assess the longitudinal validity of the GSE-UI, mean GSE-UI scores for the different response options of the combined PGI-I and CGI-I ratings were compared with self-reported changes in the mean number of UI episodes per day calculated from the bladder diaries, as well as changes in quality-of-life scores on the baseline and follow-up Incontinence Quality of Life questionnaires. Correlation between the change scores was assessed using Pearson correlation coefficients (*r*). Nine patients did not reliably complete their 72-hour voiding diaries, and these were excluded from the longitudinal validity analyses.

RESULTS

Four hundred fifty consecutive newly referred patients were screened for study eligibility. Two hundred twenty-two patients were excluded; 112 did not experience UI, an additional 84 were younger than 65, and 26 met other exclusion criteria. Of the 228 eligible patients, 89 (39.0%) agreed to participate in responsiveness testing. The three most common reasons for refusing to participate were disinterest in becoming a research subject (33.2%), busy schedules (25.1%), and poor health status (15.4%). Baseline characteristics of the study participants are shown in Table 1. The study group comprised mainly older females with variable UI severity and a predominance of mixed UI type. All patients received a teaching session and 12-week behavioral home management program consisting of pelvic floor muscle training, distraction techniques, and lifestyle modification recommendations. In addition, 21.4% of patients received anticholinergic agents to treat urge symptoms, and 15.6% were scheduled for stress incontinence surgery. UI data on eligible patients who refused to participate were not available for comparison.

Table 1. Participant Characteristics (N=89)

Characteristic	Value
SD=standard deviation; UI=urinary incontinence.	
Age, mean ± SD (range)	72.6+5.8 (65–90)
Sex, %	
Male	3.2
Female	96.8

Language, %	
French	88.9
English	11.1
Educational attainment, %	
<High school	15.1
High school	51.7
University	33.2
Mini-Mental State Examination score, mean ± SD (range)	28.9 ± 1.1 (24–30)
General health status, %	
Excellent	17.2
Very good	36.0
Good	37.6
Fair	9.2
Poor	0
Duration of urinary incontinence symptoms, years, %	
<1	3.9
1–5	61.7

>5	34.4
Frequency of UI episodes, %	
≤1 times/week	9.2
2–3 times/week	15.3
1 time/day	20.2
Several times a day	52.6
All the time	2.7
Amount of urine loss per episode, %	
A small amount	61.6
A moderate amount	29.0
A large amount	9.4
Number of pads used per day, %	
None	15.1
1	33.7
2–3	38.9
≥4	12.3
Bladder diary: number of UI episodes per day, mean ± SD, median (range)	2.3 ± 2.4, 2.0 (0–12)

Geriatric Self-Efficacy for Urinary Incontinence total score (range 0–120), mean ± SD, median (range)	65.8 ± 26.2, 68.1 (4–110)
Incontinence Quality of Life total score (range 0–100), mean ± SD, median (range)	65.3 ± 23.1, 70.4 (2–99)
UI specialist diagnosis, %	
Stress	24.7
Urge	19.1
Mixed	55.2
Obstruction	1.0
UI treatment, %	
Behavioral	100.0
Pharmacologic	21.4
Surgical	15.6

Responsiveness

At 3-month follow-up, 20 (22.5%) of patients were “very much better,” 37 (41.6%) were “a little or much better,” 23 (25.8%) had experienced no change, and nine (10.1%) were worse. Table 2 shows the mean GSE-UI improvement scores according to each improvement rating. Using the standard deviation of the GSE-UI change scores in the stable group at baseline (n=62, mean change 1.9±8.6), the Guyatt's change index for the GSE-UI was calculated as 2.6 for the clinically meaningful improvement group, and 1.5 for the any improvement group.

Table 2. Geriatric Self-Efficacy Index for Urinary Incontinence (GSE-UI) Scores According to the Combined Patient's and Clinician's Global Impressions of Improvement

Improvement Level at 3-Month Follow-Up	GSE-UI		
	Initial	Follow-Up	Change
	Mean ± Standard Deviation		
Note: Higher scores indicate greater self-efficacy for preventing unwanted urine loss.			
All participants (N=89)	65.8 ± 26.2	71.5 ± 29.0	5.8 ± 21.6
Very much better (n=20)	70.6 ± 23.3	92.8 ± 14.4	22.3 ± 24.9
Much better (n=20)	77.4 ± 21.4	85.0 ± 23.0	7.6 ± 16.1
A little better (n=17)	66.0 ± 24.9	75.1 ± 19.3	9.1 ± 14.9
No change (n=23)	58.1 ± 28.6	54.9 ± 25.0	−3.2 ± 16.6
A little worse (n=8)	47.6 ± 30.0	31.6 ± 28.1	−16.0 ± 15.8
Much worse (n=1)	55.2	18.0	−37.2
Clinically meaningful improvement group (n=20)	70.6 ± 23.3	92.8 ± 14.4	22.3 ± 24.9
Any improvement	71.6 ± 23.2	84.8 ± 20.2	13.2 ± 20.2

Improvement Level at 3-Month Follow-Up	GSE-UI		
	Initial	Follow-Up	Change
	Mean ± Standard Deviation		
group (n=57)			

Clinical Utility

Results of the ROC curves revealed an improvement of 14 points or greater on the GSE-UI to be most efficient for identifying patients who had improved by a clinically meaningful amount, with a sensitivity of 75.1% and a specificity of 78.2%. The area under the curve for the 14-point cutoff ROC curve was 0.76, indicating a 76.0% probability of selecting correctly between two patients, one of whom was very much better and the other not. For identifying patients who had experienced any degree of improvement, a 5-point increase on the GSE-UI proved to be the best cutoff score, with a sensitivity of 70.0%, a specificity of 78.3%, and a 79.0% probability of selecting a patient who improved by any amount from a set of two patients, one of whom did not improve by any amount.

Longitudinal Validity

Changes in the GSE-UI correlated strongly with changes in Incontinence Quality of Life scores (r=0.7,P<.001) and moderately with reductions in UI episodes as recorded in the bladder diary (r=0.4,P=.004).

DISCUSSION

These findings show that the 12-item GSE-UI is responsive and clinically useful for older adults experiencing UI. As a research tool, it can now be used in studies investigating self-efficacy as an explanatory psychological mechanism for improving UI status or for testing interventions that may influence self-efficacy. In practice, if it is used as an outcome measure, health providers will be able to interpret a minimal 14-point increase on the GSE-UI as evidence of a clinically meaningful treatment result. Change scores of 5 to 13 points on the GSE-UI might suggest that alternative management should be pursued. If no change or worsening UI occurs at follow-up, then a reevaluation of the treatment approach and a review of possible multifactorial factors contributing to UI should be undertaken.

The choice of a criterion standard indicator for clinically meaningful improvement in UI is complex, because no consensus exists for what constitutes meaningful change in the absence of cure. Because UI is primarily a condition that affects quality of life, many would argue that only the patient's impression of improvement should be considered when determining clinically meaningful change, but responsiveness testing for many other chronic condition instruments have traditionally taken into account the patient's, physician's, and caregiver's opinions.[21–23] For the current study, both methods (using only the patient's opinion vs the combined rating) were compared, and virtually identical results were found, with a recategorization of only five patients using the patient's global impression–only approach. Because patient ratings of improvement could not be ascertained independently of their responses to the GSE-UI in this study, it was decided to report the results using the combined rating.

The choice of Guyatt's statistic for determining responsiveness of the GSE-UI also warrants comment. Other studies have arbitrarily used the effect size, the standardized response mean, or other definitions of Guyatt's statistic for evaluating the responsiveness of instruments.[16,20,23] Measures of effect size and

standardized response means are usually used for single-group designs.[22] Guyatt's responsiveness statistic, by comparison, has the advantage of being able to account for intragroup variability over time within a stable group of patients in the denominator of the equation. This study was designed to first test for differences over time within a stable group before implementing the intervention, and it was thus possible to evaluate the responsiveness of the GSE-UI using this latter definition of Guyatt's statistic. Other investigators prefer a more-complicated version of Guyatt's statistic,[20] but because of the difficulties involved in defining a minimal clinically important change in UI status, it was decided to present the analyses as described.

Limitations of this study include the low participation rate (39%). Because it was not possible to measure self-efficacy in patients who refused to participate, it is not known whether their level of self-efficacy could have played a role in this refusal. Theoretically, eligible participants who cited busy schedules or disinterest in becoming research subjects as reasons for not participating could have had higher levels of self-efficacy than those who agreed to participate. Patients who cited poor health as a reason for refusing to participate may have had lower self-efficacy levels as a consequence of living with multiple acute or chronic diseases. Exclusion of these groups of participants from the analyses may have affected the responsiveness estimates for the GSE-UI. In addition, the self-efficacy questionnaire was completed under supervised guidance in this study, and thus its performance under self-administrated conditions was untested. Finally, the GSE-UI will not be useful for patients with cognitive impairment, a frequent co-phenomenon of UI in older adults.

In conclusion, this study shows that the 12-item GSE-UI is responsive and clinically useful as a new outcome measure for future research and practical outcome management of UI in elderly people. Its focus on an important psychological factor related to UI may help clarify the factors and mechanisms underlying dysfunctional urinary habits and their resolution in older adults.

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Author Contributions: Cara Tannenbaum designed the study, collected and analyzed data, and drafted the first version of the manuscript. Judith Brouillette collected, analyzed, and helped interpret data and helped draft the first version of the manuscript. Julie Michaud collected data and provided content expertise for the analysis. Nicol Korner-Bitensky designed the study, analyzed and interpreted data, and revised the manuscript. Chantale Dumoulin analyzed and helped interpret data, revised the first draft of the manuscript, and designed the pelvic floor muscle exercise program used in this study. Jacques Corcos aided in the design of the study, collected data, and revised the first draft of the manuscript. Le Mai Tu, Stephane Ouellet, and Luc Valiquette collected data and revised the first draft of the manuscript. Marie-Claude Lemieux aided in the design of the study, collected data, and revised the first draft of the manuscript. All authors approved the final version of the manuscript for submission.

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Appendix

Table Appendix Table A1. 12-Item Abridged Version of the Geriatric Self-Efficacy for Urinary Incontinence

Question	Score (out of 10)
How confident are you that you can hold in your urine …	
1. when you are at home and have to go to the bathroom?	
2. when you are away from home?	
3. long enough to get to the bathroom in time during the night?	
4. for at least 20 minutes when you feel the urge?	
5. when coughing?	
6. when sneezing?	
7. when laughing?	
8. when you are nervous?	
How confident are you that you can …	
9. visit places where you may have difficulty locating the bathroom?	
10. go out on social outings without worrying about urine loss?	
11. prevent urine loss without relying on pads or protection when you are at home?	

Question	Score (out of 10)
How confident are you that you can hold in your urine …	
12. prevent urine loss without relying on pads or protection when you are out?	
Total Score	

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